

# United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/587,662	06/05/2000	Jessie LS. Au	JAG-004	8925	
266 7	590 12/30/2002				
	ND SMITH, LPA		EXAMI	EXAMINER	
7700 RIVERS	MITH BUILDING EDGE DRIVE		YOUNG, JO	SEPHINE	
COLUMBUS,	JH 43233		ART UNIT	PAPER NUMBER	
			1623	11	
			DATE MAILED: 12/30/2002	U/	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.   Applicant(s)   Office Action Summary   Examiner   Art Unit   Josephine Young   1623   The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
Office Action Summary  Examiner  Josephine Young  The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
1) Responsive to communication(s) filed on <u>09 October 2002</u> .					
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims					
4)⊠ Claim(s) <u>1-89</u> is/are pending in the application.					
4a) Of the above claim(s) 25,29-32,36-39 and 48-89 is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-24,26-28,33-35 and 40-47</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12) ☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>					
2. Certified copies of the priority documents have been received in Application No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
ttachment(s)					
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5  Other:					

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

#### **DETAILED ACTION**

### Restriction Requirement Set Forth in the Office Action Mailed September 9, 2002

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Claims 29-32, 36-39, 49-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Further, Applicant's election with traverse of Species A in Paper No. 8 is acknowledged. Applicant's arguments for traversal have been considered and have overcome the requirement for the election of species as set forth in the Office Action of September 9, 2002. However, a new election of species is required as set forth below.

#### Election of Species

Claims 1-22, 28, 33-35 and 40-43 are generic to a plurality of disclosed patentably distinct species comprising methods for inhibiting or reducing the growth of a cell or for treating cancer by administering

a telomere damage-inducing agent that is (A1) paclitaxel or a derivative thereof; (A2) platinum-based agents such as cisplatin or carboplatin; or (A3) an agent other than paclitaxel or a platinum-based agent; and

a telomerase inhibitory agent that is (B1) a nucleoside or nucleotide analog such as AZT or d4T; (B2) an antisense nucleic acid; or (B3) an agent that is neither a nucleoside analog or an antisense nucleic acid.

wherein each patentably distinct species has a distinct telomere damage-inducing agent (A1, A2 or A3) and a distinct telomerase inhibitory agent (B1, B2 or B3).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct,

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applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission

may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Applicant's representative, Jerry K. Mueller, on

December 17, 2002, a provisional election was made to prosecute the invention directed to

methods for inhibiting or reducing the growth of a cell or for treating cancer comprising

administering paclitaxel (A1) and a nucleoside or nucleotide analog such as AZT and d4T (B1),

recited in claims 1-24, 26-28, 33-35 and 40-47. Affirmation of this election must be made by

Applicant in replying to this Office action. Claims 25 and 48 are withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below in <u>In re Wands USPQ2d 14000</u>. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

These factors include

- (1) quantity of experimentation necessary,
- (2) the amount of guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the predictability of the art and
- (7) the breath of the claims.

Claims 1-24, 26-28, 33-35 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of telomere length and treatment of cancer related to human breast MCF-7 cells, pharynx FaDu cells, prostate PC3 cells and ovarian SKOV3 cells, does not reasonably provide enablement for inhibiting or reducing the growth of all types of cells or for treating all types of cancer. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine which cells or cancer lines would be effected by telomerase-length reduction induced by the recited compositions for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing and determining such, as only four different cell lines were assessed, out of the numerous known cell types and in particular the numerous cell types that are implicated in the various forms of cancers, malignancies, myeloid disorders, etc.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, while certain agents and compositions are known to treat certain forms of cancer, no effective agent or composition has been found for the treatment of all cancer types. Therefore, the art at the time the invention was made fails to establish predictability with regard to the properties of the compositions needed to perform the scope of the methods as instantly claimed.

With regard to factors (3) and (7), it is noted that while there are some working examples of the treatment of cancer related to human breast MCF-7 cells, pharynx FaDu cells, prostate PC3 cells and ovarian SKOV3 cells, it is not seen as sufficient to support the breath of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Further, claims 1-24, 28, 33-35 and 40-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of telomere length and treatment of cancer related to human breast MCF-7 cells, pharynx FaDu cells, prostate PC3 cells and ovarian SKOV3 cells using a combination of paclitaxel and AZT or d4T, does not reasonably provide enablement for inhibiting or reducing the growth of a cell or for treating cancer using a combination of paclitaxel and a nucleoside or nucleotide analog other than AZT or d4T.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine which nucleoside or nucleotide analog would be useful as a telomerase inhibitor to use for inhibiting or reducing the growth of a cell or for treating cancer for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing such, as only two different nucleoside analogs were assessed, out of the numerous nucleoside and nucleotide analogs known in the art.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, various nucleoside and nucleotide analogs are known as inhibitors of polymerases such as reverse transcriptase, however, not all nucleoside and nucleotide analogs are inhibitors of polymerases. Further, there is no discernable pattern as to which nucleoside and nucleotide analog will inhibit a specific polymerase, such as reverse transcriptase, and in particular telomerase. See for example PAI et al., Cancer Research, May 1998, 58, 1909-1913 (X); and STRAHL et al., Molecular and Cellular Biology, 1996, 16, 53-56 (Y). The art at the time the invention was made fails to establish predictability with regard to the

properties of the nucleosides and nucleotides analogs needed to perform the methods as instantly claimed.

With regard to factors (3) and (7), it is noted that while there are some working examples of compositions comprising AZT or d4T, it is not seen as sufficient to support the breath of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Claims 41 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying patients having cancer, does not reasonably provide enablement for identifying patients about to have cancer.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine how to identify patients about to have cancer for which the instant invention is applicable. There has not been provided adequate guidance in the written description or in the prior art for accomplishing such.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, it is unclear as to which pre-cancerous cellular marker correlates to the development of cancer. The art at the time the invention was made fails to establish predictability with regard to the identification of patients who are about to have cancer needed to perform the methods as instantly claimed.

With regard to factors (3) and (7), there are no working examples of methods to identify a patient about to have cancer in the present application. The lack of working examples is seen as

insufficient support for the breath of the claims. It is noted that Law requires that the disclosure

of an application shall inform those skilled in the art how to use applicant's alleged discovery,

not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA

1970).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24, 26-28, 33-35 and 40-47 are rejected under 35 U.S.C. 112, second paragraph.

as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

The term "telomere damage inducing agent" render the claims in which it appears

indefinite. Since telomerase inhibitory agents can also lead to telomere damage, e.g. telomere

shortening, it is unclear in the absence of some particular distinction set forth in the claims how

the telomere damage inducing agents recited in the claims are different from telomerase

inhibitory agents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 8-10, 12-14, 16, 18, 20, 22-24, 26, 33-35 and 40-46 are rejected under 35 U.S.C. 102(b) as being anticipated by the patent US 5,756,537 to GILL (A).

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GILL teaches in Example 6 that paclitaxel can be administered concurrently with AZT for the treatment of Kaposi's sarcoma (KS). See in particular, col. 9, lines 40-42. GILL further discloses that paclitaxel can be administered orally, via inhalation, intravenously, intramuscularly, intradermally, intraperitoneally, and subcutaneously using various carriers (col. 5, line 19 to col. 6, line 4).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-24, 26-28, 33-35 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over the patent US 6,150,398 to VANDE WOUDE et al. (B) in view of THE MERCK INDEX, 1996, 7117, 8958 and 10252 (W).

Applicant claims methods for the for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel and a nucleoside or nucleotide analog such as AZT or d4T, either serially or concurrently. Further, Applicant claims the methods wherein either each or both of the active agents are administered locally, systemically or regionally. Applicant also claims the methods wherein either each or both of the active agents are administered as a time-release formulation. Finally, Applicant claims methods wherein one of the agents can be administered in sub-therapeutic dosages.

VANDE WOUDE teaches that paclitaxel or a paclitaxel derivative can be used with an agent that effects the G<sub>1</sub> or S phase of the cell division cycle. See Abstract. In col. 10, Table 3, VANDE WOUDE discloses that paclitaxel effects the M-phase, while methotrexate, 5'-fluorouracil and cytosine arabinoside effect the G<sub>1</sub> or S phase by altering DNA synthesis. Further, in col. 11, lines 37-50, VANDE WOUDE discloses that the growth of oncogene-transformed cells may be completely inhibited by the combination of a drug having S-phase activity and a subtherapeutic amount of a drug having M-phase activity.

VANDE WOUDE does not explicitly disclose AZT or d4T as inhibitors of the G<sub>1</sub> or S phase of cell division. Further, VANDE WOUDE does not specifically disclose that each or both of the active agents can be administered locally, systemically or regionally. VANDE WOUDE also does not specifically disclose that each or both of the active agents can be administered as a time-release formulation.

THE MERCK INDEX teaches that zidovudine (AZT) and stavudine (d4T) are polymerase inhibitors. See entry nos. 10252 and 8958 respectively. Further, THE MERCK INDEX discloses that AZT has antiviral, antimetabolite and antineoplastic activity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use AZT or d4T as inhibitors of the G<sub>1</sub> or S phase of cell division. A skilled artisan would have been motivated to reduce or inhibit cell growth or to treat cancer with AZT or d4T and paclitaxel, as AZT and d4T are both known polymerase inhibitors, i.e. inhibitors of the G<sub>1</sub> or S phase of cell division. Further, the administration of the active ingredients locally, systemically or regionally, as well as the administration of the active ingredients as a timerelease formulation, is well known to one of ordinary skill in the pharmaceutical area. Therefore, methods limited to these modes of administration are considered a choice of experimental design, and are well within the purview of the prior art.

Claims 1-24, 26, 28, 33-35 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article MELANA et al., Clinical Cancer Research, March 1998, 4, 693-696 (V) in view of THE MERCK INDEX (W).

Applicant claims methods for the for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel and a nucleoside or nucleotide analog such as AZT, either serially or concurrently. Further, Applicant claims the methods wherein either each or both of the active agents are administered locally, systemically or regionally. Applicant also claims the methods wherein either each or both of the active agents are administered as a time-

release formulation. Finally, Applicant claims methods wherein one of the agents can be administered in sub-therapeutic dosages.

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MELANA teaches that 3'-azido-3'-deoxythymidine (AZT) is effective in inhibiting the growth of four breast cancer cell lines and T4 cell leukemia. See Abstract. Further, in the Abstract, MELANA discloses that AZT inhibits telomerase activity. Finally, MELANA teaches that AZT can be used, alone or in combination, as an anti-breast cancer agent.

MELANA does not explicitly state methods for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel in particular with AZT. MELANA does not specifically disclose that each or both of the active agents can be administered locally, systemically, or regionally. MELANA also does not specifically disclose that each or both of the active agents can be administered as a time-release formulation.

THE MERCK INDEX teaches that paclitaxel is a known antineoplastic for the treatment of breast and ovarian cancer. See entry no. 7177.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made to use AZT in combination with a known anti-breast cancer agent, such as paclitaxel, for the treatment of breast cancer. A skilled artisan would have been motivated to use paclitaxel in combination with AZT as paclitaxel is well known as an antineoplastic for the treatment of breast and ovarian cancer, and combination therapies are well known within the field of cancer therapeutics. Further, the administration of the active ingredients locally, systemically or regionally, as well as the administration of the active ingredients as a timerelease formulation, is well known to one of ordinary skill in the pharmaceutical area. Therefore,

methods limited to these modes of administration are considered a choice of experimental design, and are well within the purview of the prior art.

Claims 1-24, 26-28, 33-35 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article MELANA (V) in view of THE MERCK INDEX (W) and further in view of the article PAI et al., Cancer Research, May 1998, 58, 1909-1913 (X).

Applicant claims methods for the for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel and a nucleoside or nucleotide analog such as AZT or d4T, either serially or concurrently. Further, Applicant claims the methods wherein either each or both of the active agents are administered locally, systemically or regionally. Applicant also claims the methods wherein either each or both of the active agents are administered as a time-release formulation. Finally, Applicant claims methods wherein one of the agents can be administered in sub-therapeutic dosages.

As set forth supra, MELANA in view of THE MERCK INDEX teaches that AZT can be administered with paclitaxel for the treatment of breast cancer.

MELANA in view of THE MERCK INDEX does not disclose that d4T is a telomerase inhibitor and thus can be used in combination with paclitaxel.

PAI teaches that telomerase is a reverse transcriptase. See Abstract. Further on page 1912, Table 1, PAI discloses that 2',3'-dideoxy-2',3'-didehydrothmidine triphosphate (d4TTP) is an inhibitor of telomerase activity.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made that d4T, a telomerase inhibitor like AZT, would be useful in the treatment

of cancer. Further, a skilled artisan would have been motivated to use such an inhibitor in combination with paclitaxel to inhibit or reduce cell growth and/or to treat cancer, as such combination therapies are prevalent within the art, as set forth supra. Further, the administration of the active ingredients locally, systemically or regionally, as well as the administration of the active ingredients as a time-release formulation, is well known to one of ordinary skill in the Therefore, methods limited to these modes of administration are pharmaceutical area. considered a choice of experimental design, and are well within the purview of the prior art.

Claims 1-4, 7-28, 33-35 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over GILL (A) in view of THE MERCK INDEX (W).

Applicant claims methods for the for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel and a nucleoside or nucleotide analog such as AZT or d4T, either serially or concurrently. Further, Applicant claims the methods wherein either each or both of the active agents are administered locally, systemically or regionally. Applicant also claims the methods wherein either each or both of the active agents are administered as a timerelease formulation. Finally, Applicant claims methods wherein one of the agents can be administered in sub-therapeutic dosages.

As set forth supra, GILL teaches in Example 6 that paclitaxel can be administered concurrently with AZT for the treatment of Kaposi's sarcoma (KS). See in particular, col. 9, lines 40-42. GILL also discloses in that same section that other antiretroviral agents can be used in combination with paclitaxel. GILL further discloses that paclitaxel can be administered orally, via inhalation, intravenously, intramuscularly, intradermally, intraperitoneally, and subcutaneously using various carriers (col. 5, line 19 to col. 6, line 4).

GILL does not explicitly teach that the agents can be administered serially rather than concurrently. GILL also does not teach that d4T in particular can be administered rather than AZT.

THE MERCK INDEX teaches that stavudine (d4T) is a reverse transcriptase inhibitor for the treatment of an HIV infection. See entry no. 8958.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use another known anti-HIV agent similar to AZT, such as d4T, in combination with paclitaxel, as GILL discloses that other antiretroviral agents are viable for the treatment of Kaposi's sarcoma. A skilled artisan would have been motivated to use any known antiviral agent for the treatment of HIV concurrently or serially with paclitaxel for the treatment of HIV-related Kaposi's Sarcoma, as such regimes would be useful both in the treatment of Kaposi's Sarcoma and in the treatment of HIV. Concurrent and serial treatments are frequently used and very well known in the art pertaining to viral and cancer therapeutics. Therefore, methods regarding the various modes of administration are considered a choice of experimental design, and are well within the purview of the prior art

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Claims 1-89 are pending. Claims 25, 29-32, 36-39 and 48-89 are withdrawn. Claims 1-

24, 26-28, 33-35 and 40-47 are rejected. No claims are allowed.

This case has been transferred to Examiner Young. Accordingly, any inquiry concerning

this communication or earlier communications from the examiner should be directed to

Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be

reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 for regular

communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1235.

JΥ

December 19, 2002

JAMES O. WILSON

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SUPERVISORY PATENT EXAMINER

PECHNOLOGY CENTER 1600